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| EXAMINER | |
|---|---|
| BLANCHARD, DAVID J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1643 | |

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/522,900 | MCCORMICK ET AL. | |
| | Examiner | Art Unit | |
| | David J. Blanchard | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6-23,29,37-40 and 54-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-23,29,37-40 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 August 2005 has been entered.

2. Claims 5, 24-28, 30-36 and 41-53 have been cancelled.

Claim 1 has been amended.

Claims 55-56 have been added.

3. Claims 1-4, 6-23, 29, 37-40 and 54-56 are pending and under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Objections.

### *Objections/Rejections Withdrawn*

6. The objection to the specification under 35 U.S.C. 132 for introducing new matter in the amendment filed 11/17/2004 is withdrawn in view of applicants amendments to the first line of the specification, i.e., removal of the incorporation by reference statement.

7. The rejection of claims 1-10 and 19 under 35 U.S.C. 101 as being drawn to non-statutory subject matter as lacking the hand of man is withdrawn in view of the amendments to claim 1.

8. The rejection of claims 1-4, 6-23, 29, 37-40 and 54 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "at risk of developing a tumor, encoded at least in part by a nucleic acid in the cells of said tumor" is withdrawn in view of applicants arguments.

9. The rejection of claim 1 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "said nucleic acid" is withdrawn in view of applicants arguments.

10. The rejection of claim 54 under 35 U.S.C 102(b) as being anticipated by Caspar et al is withdrawn in view of applicant's arguments.

11. The rejection of claim 54 under 35 U.S.C 102(b) as being anticipated by Hawkins et al is withdrawn in view of applicant's arguments.

12. The provisional rejection of claims 1-4, 6-23, 29, 37-40 and 54 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/067,790 in view of Hawkins et al is withdrawn in view of the cancellation of claims 1-40 in copending Application No. 10/067,790.

***Response to Arguments***

13. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims 55-56 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "encoded at least in part" is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that claim 1 is clear, but to be redundant the claim has been amended to recite that the "part" of the nucleic acid in the cells of the tumor encodes a surface immunoglobulin epitope and since B-cell lymphomas are generally clonal this language is quite precise. In response to this argument the claim language still recites that the polypeptide self-antigen is encoded at least in part and it remains unclear what encodes the rest of the polypeptide self antigen. If the nucleic acid in the cells of the tumor only encodes part of the polypeptide self-antigen, what encodes the rest of the polypeptide self-antigen?

14. The rejection of claim 23 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "at least about" is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that from earlier claim 20, from which claim 23 depends the amount is sufficient to induce a polyclonal anti-idiotypic antibody response or a cell mediated immune response. The response also states that the functional range is further redefined by an amount, which is required to produce the recited function. In response to this argument, definition of a specific concentration range

based on the activity of the administered polypeptide provides no clear indication as to what the range actually is. There is nothing in the specification as to what specific range of the administered polypeptide is covered by the term "about" and the specific range is not adequately defined by the claim. In view of the close prior art (e.g., Hawkins et al and Caspar et al) applied in the present application, and the absence of a clear definition as to what specific range is covered by the term "about" the claims are indefinite. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) (MPEP 32173.05(b)). The applied art of Hawkins et al teach the administration of a scFv at a concentration of 12.5 μg and Caspar et al teach the administration of a scFv at a concentration of 50 μg.

15. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims 55-56 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "a nucleic acid encoding a peptide sequence overlapping a peptide sequence encoded by said nucleic acid in the cells of said tumor" is maintained.

The response field 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response points out that claim 1 recites "A purified polypeptide..., encoded at least in part by a nucleic acid..." and it should be clear to all that the nucleic acid at least partially encodes the claimed polypeptide and applicant states that the nucleic acid encodes a peptide with only some sequence overlap to the claimed polypeptide. In response to this argument the claims remain ambiguous because the part or parts that are encoded by the nucleic acid in the tumor cells are not defined by

the claims and in turn, the nucleic acid encoding a peptide sequence overlapping is also unclear and undefined. Further, it is unclear what the overlapping sequence actually is and what the overlap region is or is the overlapping peptide sequence the same as the polypeptide self antigen encoded by the nucleic acid in the cells of the tumor in which case it would be identical and not overlapping. How does the overlapping peptide sequence relate to the polypeptide self-antigen sequence encoded by the nucleic acid in the cells of the tumor and what other sequence is encoded by the nucleic acid that encodes the overlapping peptide sequence? The response also points out that the specification makes clears that applicant's preferred embodiment is a single chain antibody, which uses part of the sequences from two different genes, VH and VL connected by a synthetic linker. In response to this argument, applicant is reminded that while the claims are read in light of the specification, limitations from the specification are not read into the claims (see MPEP 2111).

16. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims 55-56 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that applicant has given the composition to patients who at the time were in remission with no sign of current disease and the

examples in the specification demonstrate the use and usefulness of the claimed vaccine in humans. Further, the response states that the results of FDA phase I clinical trials have been published with the vast majority of patients displaying a tumor specific immune response in response to vaccination. In response to these arguments the issue is not whether the administration of the claimed polypeptide self-antigen will elicit an anti-B cell lymphoma immune response, but rather, the issue is whether or not administering the claimed polypeptide self-antigen can prevent or cure B-cell lymphomas in patients. Again, the instant claims are drawn to a B-cell lymphoma tumor specific "vaccine" composition, which broadly encompasses preventing a B-cell lymphoma in subjects that do not yet have cancer, as well as completely curing cancer and preventing relapse. Further, applicants base claim, claim 1, recites a subject "at risk of developing the B-cell lymphoma tumor", which clearly encompasses treating a person who does not yet have cancer, as well as completely curing cancer and preventing any relapse. There is no teaching in the prior or post-filing art or in applicant's specification indicating that B-cell lymphomas can be prevented or cured, thus indicating the high degree of unpredictability of preventing and curing cancer. In fact, a "vaccine" would encompass all of the problems associated with treating cancer, as well as additional obstacles such as preventing the events that lead to transformation of a normal cell into a cancerous cell including preventing genetic mutation, and immortalization. Amending the claims to recite a "composition" or "therapeutic composition" for the term "vaccine" would overcome this rejection.

17. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims 55-56 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that the requirement for both VH and VL domains in the polypeptide self-antigen is speculation by the examiner and while one may wish to have as much of the idiotype as possible, it is not resolved that the full complement is needed. In response to this argument, Benvenuti et al (cited previously in the Office Action mailed 8/17/04) makes clear that the immune response (i.e., anti-idiotypic antibodies) is directed exclusively against conformationally combined VL/VH determinants (see page 1557, right column), which evinces that the conformationally combined VH/VL pairs are required to mimic the natural idiotype of the surface immunoglobulin expressed in B-cell lymphomas. According to Benvenuti et al "The anti-idiotype immune response was directed exclusively at the original immunising VL/VH combination, with complete absence of antibodies recognizing determinants in any of the single V regions displayed in the context of a different idiotype." (see page 1558). Thus, Benvenuti et al, demonstrates that the parental V regions association is required to induce anti-idiotype antibodies and these antibodies are exclusively against conformational combined VL/VH determinants (see page 1557 and abstract). Thus, it is not mere speculation on the part of the examiner, but the explicit teachings of Benvenuti

et al that conformationally combined parental VH/VL pairs are required to mimic the natural idiotype of the surface immunoglobulin expressed by B-cell lymphomas. Further, it is respectfully noted that the teachings in applicant's disclosure are limited to idiotype compositions comprising VH/VL pairs (i.e., scFv) for the induction of an immune response that is specific for the unique idiotypes expressed on B cell lymphomas.

Applicant also argues that the specification shows that a single chain antibody (VH-linker-VL) alone is adequate even though it is an artificial molecule with considerably less than naturally occurring two-chain tumor antigen. This is exactly the point of the present enablement rejection. It is reiterated that Applicant is enabled for a purified polypeptide self-antigen comprising both VH and VL domains (i.e., scFv), wherein all of the heavy and light chain CDRs are in their proper order and in the context of framework sequences, which maintain their required conformation and therefore, mimic the natural idiotype expressed on the surface of B cell lymphomas. Administration of such an idiotype composition induces a specific immune response against the idiotypes expressed on B cell lymphomas. Applicant's specification acknowledges that both the VH and VL domains are critical in mimicking the idiotype of the naturally expressed Ig on the surface of B cell lymphomas. The specification at page 45, lines 16-19, states that "The conformation of the relevant epitopes (idiotypes in the case of an idiotypic scFv protein characteristic of a B cell lymphoma) in solution should resemble or mimic the same epitopes of the native protein as they appear on the surface of the tumor cell" and at page 16 of the specification indicates that an idiotype is formed by the association of the hypervariable or complementary determining regions of

VH and VL domains (see page 16 of the specification) and at page 51, lines 7-10, "However, because most idiotypes are expected to be the result of the interaction of the VH with the VL domain, more preferred compositions combine both these regions."

The present claims still broadly encompass a polypeptide self-antigen that includes an epitope or epitopes of a surface immunoglobulin. Claim 1 encompasses using any epitope(s) from the constant region or the hinge or the frameworks or the CDRs, which would not produce an idiotype that mimics the natural surface Ig expressed on B-cell lymphomas. Further, the claims encompass an idiotypic eptiope of a single V region, of any two V region domains (i.e., VH-VH), and of only part of the VH and only part of the VL domains, which encompasses incomplete VH and VL domains that do not contain the full complement of 6 CDRs, from both the heavy chain and light chain. Applicant has not provided any objective evidence that epitopes from the constant regions or hinge region or frameworks, or from a single V region, or from just any two V regions (i.e., VH-VH or VL-VL) or from only part of the VH and VL domains of B-cell lymphoma surface immunoglobulins result in conformational dependent epitopes (idiotypes) mimicking the surface immunoglobulins expressed on B cell lymphomas, and effectively produce a specific immune response against the B cell lymphomas. Further, applicant has not provided objective evidence that incomplete VH and VL scFvs connected via applicants linkers or scFvs comprising two VH domains (i.e., VH-VH) or two VL domains (i.e., VL-VL) connected via applicant's linkers result in idiotypes that mimic the natural surface Ig expressed in B-cell lymphomas. It is unlikely that epitopes derived from any part of the surface immunoglobulin or epitopes that do not contain

complete VH and VL domains, would mimic the idiotypes of native surface immunoglobulins expressed in B-cell lymphomas. As evidenced by Casper et al (previously cited on PTO-892 mailed 8/17/2004), "a change of one or two amino acids in the second complementarity-determining region (CDR2) of the heavy chain seemed to be responsible for the loss of binding to the treatment of MoAb." (anti-idiotypic antibody) (see page 3699, left column). Thus, Casper et al teach that even minor structural changes (i.e., one or two amino acids) in a single CDR result in a structural change such that the idiotype of the surface Ig no longer resembles the idiotype of the original surface Ig expressed on B-cell lymphomas.

There is insufficient evidence or nexus for one of skill in the art to extrapolate the teachings of the specification which are limited to using single-chain antibodies (scFvs) (comprising both the VH and VL domains of immunoglobulins expressed on the surface of B cell lymphomas) to mimic the idiotypes of surface immunoglobulins expressed on B cell lymphomas to the presently claimed polypeptide self-antigens comprising an epitope or epitopes derived from any part of the surface immunoglobulin or epitopes that do not contain complete VH and VL domains, and do not mimic the idiotypes of native surface immunoglobulins expressed in B-cell lymphomas for producing a specific immune response against B cell lymphomas.

Again, Applicant is enabled for a scFv idiotype composition comprising both VH and VL domains obtained from lymphoma cells of a subject, wherein the heavy and light chain CDRs are in their proper order and in the context of framework sequences, which

maintain their required conformation and therefore, mimic the natural idiotype expressed on the surface of B-cell lymphomas.

18. The rejection of claim 54 and applied to newly added claim 56 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement for introducing new matter is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that support for the language 'not fused or conjugated to another polypeptide" is explicitly and implicitly found in many places. Applicant notes that at the top of page 5, mention is made of idiotype vaccines that are conjugated and the first sentence of the next paragraph indicated that that method is not acceptable. Applicant also cites page 21, lines 4-6 as stating "These products are defined as being "inherently immunogenic" so that potent immune responses to them are generated without the need for conjugation to carrier molecules...". Further, applicant argues that support for the language "not fused" may be found at page 51, lines 11-14 states that the protein/peptide is "...so effective immune responses are generated in the absence of exogenous (or fusion protein)...". Upon review of the as-filed specification as cited by applicant, there is insufficient written support for the presently claimed polypeptide self-antigen not fused or conjugated to another polypeptide. The disclosure of the polypeptide as being inherently immunogenic so that effective immune responses are generated without the need for fusion to another polypeptide or an adjuvant is with respect to plant expression systems and the inherent

immunogenicity of the polypeptide produced thereby. The rejected claims and the base claim (claim 1) from which they depend do not require plant expression of the presently claimed polypeptide, which confers the inherent immunogenic properties of the presently claimed polypeptide in the absence of conjugation to another polypeptide. Further the disclosure at page 5 of the specification indicating that current methods for producing custom tumor vaccines as being insufficient to meet current and future demand does not provide adequate written support for the presently claimed polypeptide not conjugated or fused to another polypeptide. When read in the context of the surrounding text of pages 5-6, it is the production of the idiotype polypeptide that is limiting and not necessarily conjugation to another polypeptide. The disclosure as cited by applicant would have led the skilled artisan to seek alternative methods for the production of the idiotype and would not have led the skilled artisan to the presently claimed polypeptide, not conjugated or fused to another polypeptide.

19. The rejection of claims 1-4, 6-13, 17-23, 29 and 38 under 35 U.S.C 102(b) as being anticipated by Caspar et al is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that the scFv-GM-CSF taught by Caspar et al is different from the claimed polypeptide because the present invention is capable of inducing an immune response without an adjuvant. As noted in the previous Office Actions, the phrase "capable of" is non-limiting because an element "capable of" performing a function is not a positive limitation, but only requires the ability to so

perform. As acknowledged by applicant, Casper et al teach a scFv (adenovirus) without the GM-CSF, which when expressed in vivo induced an anti-idiotype immune response, providing evidence that the scFv is "capable of" inducing an immune response without the need for adjuvant or other immunostimulatory material (see Figures 2 and 3) (see bridging lines of pages 10-11 of the applicant's response filed 8/2/05). Further, applicant is reminded that the claimed polypeptide self-antigen "includes...", which is equivalent to "comprising" and is inclusive or open-ended and does not exclude additional unrecited elements (see MPEP 2111.03). Therefore, the scFv-GM-CSF taught by Casper et al reads on the claimed polypeptide and Caspar et al teach that the scFv-GM-CSF fusion protein is purified by immunoaffinity chromatography and 50 μg was administered three times, two weeks apart (see page 3701, top left column). Thus, applicant's arguments that the presently claimed polypeptide is purified and distinguishable from the prior art is not persuasive and the rejection is maintained.

20. The rejection of claims 1-4, 6-12, 17-23, 29 and 37-38 under 35 U.S.C 102(b) as being anticipated by Hawkins et al is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response states that the claims are directed to a purified polypeptide, not a DNA construct or a potential polypeptide made in vivo but never purified. In response to this argument, it is reiterated that Hawkins et al teach a scFv that is an idiotypic determinant (i.e., epitope) of an immunoglobulin expressed on the surface of a B cell lymphoma and the scFv is purified and administration of the scFv

generated an anti-idiotypic response, clearly indicating that the scFv was in correctly folded form and mimicked the idiotype of the immunoglobulin expressed on the B cell lymphomas (see pages 19-20). The response states that without a showing of a polypeptide with the claimed features, Hawkins et al do not anticipate the claims and the other comments provided before still apply. In response to this argument, the following is reiterated for applicant's convenience.

Hawkins et al teach a scFv that is an idiotypic determinant of an immunoglobulin expressed on the surface of a B cell lymphoma (see entire document, particularly Figure 1 and pages 2-22). Thus, the scFv includes an epitope or idiotype that is unique to B cell lymphoma cells, includes both the VH and VL domains, which are two peptide domains, two V region domains, are at least part of the VH and part of the VL and include all six CDRs, which meets the limitation of at least one CDR, wherein the CDR is CDR2 (claims 9-10). Hawkins et al teach the scFv in PBS (i.e., integrated into a carrier; in solution; a pharmaceutically acceptable carrier or excipient), mixed with complete Freud's adjuvant (further comprising an adjuvant; claim 37) and administered to a mammalian host by subcutaneous immunization at 12.5 μg three times about two weeks apart (see page 19). 12.5 μg of the scFv is interpreted to be at least about 15 μg. Hawkins et al teach that administration of the scFv generated a polyclonal anti-idiotypic antibody response, which was detected by testing the sera of the host by ELISA (enzyme immunoassay) and flow cytometry (FACS analysis) (see pages 20-21 and 7). Also, since the scFvs taught by Hawkins et al contained the complete VH domain, it is inherent that the complete VH domain includes CDR2, absent evidence to

the contrary. Finally, Hawkins et al teach that the scFv (i.e., polypeptide self-antigen) may be co-administered with an immunomodulatory cytokine as a scFv fusion or separate from the scFv (see pages 2-3).

The intended use recitations including, "useful as a tumor-specific vaccine in a subject with a tumor or at risk of developing a tumor" is given no patentable weight (see MPEP 2111.02). Further, the phrase "capable of" (see claim 1, part d) is non-limiting because an element "capable of" performing a function is not a positive limitation, but only requires the ability to so perform. To this extent, Hawkins et al teach expression of the scFv, absent an adjuvant or other immunostimulatory materials, in vivo produced anti-idiotypic antibodies that recognized the native Ig expressed on the surface of lymphoma cells (see pages 21-22). Therefore, the scFv taught by Hawkins et al is "capable of" inducing an immune response in a mammal without the need for adjuvant or other immunostimulatory materials. Additionally, claims 1-3 are drafted in the product-by-process format. The reference does not describe the production of the molecule using the methods identical to that is recited in claims 1-3. However, the recitation of the process limitations in claims 1-3 are not viewed as positively limiting the claimed product absent a showing that the process of making recited in claims 1-3 imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is placed upon Applicant to establish a patentable distinction between the claimed and references products.

21. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims55-56 under 35 U.S.C. 103(a) as being unpatentable over Casper et al in view of Fiedler et al and Tang et al and Hakim et al is maintained.

The response filed 8/2/2005 has been carefully considered, but is deemed not to be persuasive. The response states that the previous Office Action mailed 2/2/2005 repeats applicant's arguments and mischaracterizes others and applicant states that rather than rebutting these arguments, the examiner's position is a simple conclusion without support for the claimed features not taught or suggested by any of the applied references. In response to these arguments, applicant has not pointed to any feature or features that are not taught or suggested by the combination of references cited by the examiner. Further, in order to have compact prosecution in the present application, applicant is encouraged to clarify their position or contact the undersigned if applicant feels their position has been mischaracterized by the examiner. Applicant has not provided any new or additional arguments to support non-obviousness and as such the rejection is maintained for reasons of record and the examiners arguments in the previous Office Action (mailed 2/2/05) are incorporated by reference.

***New Grounds of Objections***

22. Claim 55 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 1, from which claim 55 depends

recites that the polypeptide self-antigen is purified, however, dependent claim 55 recites a plant cell extract composition containing the polypeptide self-antigen, which is not in purified form and thus, does not does not include every limitation of the claim on which it depends and as such does not further limit the subject matter of previous claim 1.

***Conclusions***

23. No claim is allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tony Parks for Art Unit 1643 whose telephone number is 571-272-0543.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

SHEELA HUFF
PRIMARY EXAMINER